Summary

A new study -- the largest ever conducted on environmental tobacco smoke (ETS) -- has found no increased risk of lung cancer among nonsmokers exposed to a spouse's smoking at home.

This study, recently published in the British Journal of Cancer, follows two other recent studies that also found no increased risk of lung cancer from ETS exposure. One of those studies has been published; the other is in the process of publication.

These recent studies on ETS, reported since the release of the U.S. Environmental Protection Agency's (EPA) draft risk assessment on ETS, found no increased risk of lung cancer among nonsmokers exposed to a spouse's smoking at home. The impact of these studies on the indictment of ETS contained in the EPA's draft risk assessment is problematic for scientists scheduled to consider a Science Advisory Board Committee Report on the risk assessment.

Not only do these studies report new data which are contrary to the risk attributed to exposure to ETS in the draft risk assessment, but the latest was conducted by a member of the EPA's own Science Advisory Board (SAB) which examined the draft risk assessment on ETS on December 4-5, 1990. Although the SAB Committee Report has yet to be made public, the scientist, Dr. William Blot of the National Cancer Institute, did not discuss his study nor its findings during the SAB Committee's meeting on the EPA's draft report in December.

Next month, the Executive Committee (EC) of the SAB will hold its quarterly meeting. At that time, the chairman of the SAB Committee which reviewed the ETS draft risk assessment in December will submit the Committee's report to the EC. The EC will make a determination whether the SAB Committee's Draft Report will be approved for submission to the EPA.

Without inclusion of the latest data, the EPA's risk assessment could be viewed as incomplete. Adding the studies now would logically require reconsideration of the draft report's analysis and conclusions.

The EPA's draft risk assessment consists of a statistical analysis of 23 studies conducted both in the United States and in other countries. Most of the studies were of nonsmoking women with lung cancer who lived with men who smoked. In its assessment, the EPA considered only spousal smoking as an index of exposure to ETS, and did not consider other exposures both within and outside the home.

Critics of the report have condemned the use of this single index as well as the mixing of U.S. and foreign studies. In other countries, particularly some in Asia, lifestyle and environmental factors may contribute to increased incidence of lung cancer. For example, two of these factors are the use of coal-burning stoves or heating devices and the use of cooking techniques which produce oil vapors. The studies included in the EPA's draft risk assessment did not consider such confounding factors on a uniform and consistent basis. In fact, the EPA violated its own guidelines by not addressing the impact of confounding factors in evaluation of the epidemiological studies on ETS.

The three new studies published since the EPA drafted its report suggest that lifestyle practices (e.g., cooking and heating fuels) may increase the risk for lung cancer in nonsmoking women. These results underscore the importance of addressing these confounding factors in evaluation of the ETS epidemiological studies.

Meanwhile, analysis of those studies conducted only in the United States shows no statistically significantly increased risk for lung cancer among nonsmokers exposed to ETS either from a spouse's smoking or from exposure in the workplace or in social settings.

Several of the studies in the EPA's draft report which claimed a statistically significant risk of lung cancer for nonsmokers exposed to ETS were conducted in Asia. The largest of these earlier studies, by Dr. Takeshi Hirayama, received extensive discussion and treatment in the EPA's draft risk assessment. The EPA draft report referred to it the "flagship study" on ETS. Ironically, at the December meeting of the SAB Committee, discussion of the risk assessment included strong suggestion that the Hirayama study should be excluded. Citing a critical analysis of the Hirayama study, one SAB Committee member said, "the Hirayama study should not be cited or not be depended upon heavily in this report."

The three new studies were all conducted in Asia; however, unlike some of the prior studies relied upon by the EPA in its draft risk assessment, the new studies took into account other lifestyle and environmental factors considered to be potential

risk factors for lung cancer. When these variables were included in the analysis, the studies reported that ETS did not pose an increased risk for lung cancer.

Questions

1. Will the SAB Executive Committee include the new studies in the risk assessment? If not, why not?

2. Were the new studies included or discussed in the SAB Committee report?

3. Will the EPA follow the recommendation of members of the SAB Committee regarding exclusion of the Hirayama study? If not, why not?

4. Will the EPA address confounding factors in its evaluation of the epidemiologic research as required by the EPA cancer guidelines?

Bullet Points

1. Three new studies on ETS report no increased risk of lung cancer in nonsmokers exposed to a spouse's smoking.
2. All three studies were conducted in Asia, where earlier studies cited in the EPA's draft risk assessment claimed to demonstrate an increased risk of lung cancer.
3. The three new studies are larger and, many might urge, better conducted than the earlier studies.
4. The most comprehensive of the three new studies was conducted by a member of the EPA Science Advisory Board Committee which met to review the draft risk assessment last December. Although the SAB Committee's report has not yet been made public, the SAB member, Dr. William Blot, did not discuss or mention this study or its findings during the December discussions of the EPA report.
5. Critics of the EPA risk assessment have condemned mixing U.S. and foreign studies because lifestyle factors in other countries could be potential risk factors for lung cancer. When taking into account these other risk factors, the new studies reported no increased risk.
6. Analyses of the U.S. studies have consistently reported no significant increased risk of lung cancer for nonsmokers exposed either to a spouse's smoking, to ETS in the workplace, or to ETS in social situations.

Study Findings

The three new studies are listed below with a brief summary of each study's findings.

1. Sobue, T, Suzuki, R., et al., "Passive Smoking Among Nonsmoking Women and the Relationship Between Indoor Air Pollution and Lung Cancer Incidence -- Results of a Multicenter Case-control Study"' Gan to Rinsho 36(3): 329-333, 1990 (translation).

Conclusions:

This case-control study (120 cases) reported no increased risk for lung cancer attributed to ETS from spousal smoking. The study reported that past use of straw or wood as cooking fuel may be a risk factor for lung cancer among nonsmoking women, with a statistically significantly elevated relative risk.

2. Wu-William, A.H., Dai, X.D., Blot, W., et al., "Lung Cancer among Women in North-East China", British Journal of Cancer 62: 982-987, 1990.

Conclusions

This study investigated the association between numerous potential risk factors and lung cancer incidence in women in Shenyang and Harbin, two industrial cities in China. Elevated risks were reported for exposure to air pollution from coal-burning heating and cooking devices and for exposure to cooking oil vapors. No increase in risk was reported for exposure to spousal smoking.

3. He,X., Chen, W., et al., "An Epidemiological Study of Lung Cancer in Xuan Wei County, China: Current Progress (I)", Archives of Environmental Health 46 (2): 118-119, 1991 (abstract).

Conclusions

In women in Xuan Wei County, China, a statistically significant association was reported between chronic bronchitis and family history of lung cancer and lung cancer incidence. The authors also report that lung cancer was associated with the duration of cooking food, but not with "passive smoking".